89. (New): A vaccine composition comprising a live attenuated rotavirus population according to claim 57, designated as P43 and deposited under accession number ECACC 99081301.

90. (New): A vaccine composition comprising a live attenuated rotavirus variant designated P43 and deposited with the ECACC under accession number 99081301, rotavirus progeny and immunologically active derivatives thereof and materials obtained therefrom.

91. (New): A vaccine composition comprising a live attenuated rotavirus reassortant comprising at least one antigen or at least one segment of the rotavirus variant P43 of claim 89.

REMARKS

Claims 40-78 are pending in this application and are subject to a restriction requirement. The Applicants herein delete Claim 72. The Applicants herein amend the instant claims to render the elected claims dependent and to comply with the sequence listing rules. The Applicants also herein amend the specification to comply with the sequence listing rules. Further, the Applicants herein add new Claims 79-91, which incorporate the limitations of non-elected Claims 40-52. Therefore, these amendments raise no issues of new matter.

SEQUENCE COMPLIANCE

The Examiner notes that Claim 49 makes reference to figures, and requests that the Applicants amend Claim 49 to insert the corresponding sequence identifier numbers. The Applicants herein amend Claim 49 accordingly.

The Examiner also objected to the specification for failing to adhere to the requirements of the sequence rules. Under 37 C.F.R. § 1.821(d), the Applicants must append sequence identifier numbers to all mentions of specific sequences in the claims and specification, including the figures. In response to this objection, the Applicants herein amend the specification accordingly.

ELECTION/RESTRCTION

A requirement for restriction has been made under 35 U.S.C. §§ 121 and 372 (37 C.F.R. §1.499) between the inventions of:

I. Claims 40-52, drawn to an attenuated human rotavirus population comprising at least one of the rotavirus proteins.

II. Claims 53-56, drawn to a method of production of an attenuated human rotavirus population.

III. Claims 57-76, drawn to a vaccine composition comprising a live attenuated human rotavirus and an antacid.

IV. Claim 77, drawn to a method of manufacture of a rotavirus vaccine comprising admixing a lyophilized live attenuated human rotavirus with an antacid and a viscous agent.

V. Claim 78, drawn to a method of preventing rotavirus infection in humans by administering to a human subject in need thereof an effective amount of a vaccine.

Upon review of the Detailed Action provided by the Examiner, the Applicants provisionally elect the subject matter of Group III., Claims 57-76, with traverse. The Examiner objects to the instantly pending claims for a lack of single general inventive concept under PCT rules 13.1 and 13.2 over Clark, *et al.* (US 5,626,851). Specifically, the Examiner argues that, although the common technical feature among the instantly claimed inventions is an attenuated rotavirus comprising an antigen from a human rotavirus, it is not an improvement over Clark, *et al.*

The Applicants respectfully disagree with the Examiner's arguments. The subject matter of the present patent application relates to attenuated human rotavirus. By contrast, Clark, *et al.* does not teach human reassortants; rather, Clark, *et al.* teaches animal (bovine)/human reassortants. The contribution that the claimed invention makes to the art is to provide a novel rotavirus vaccine that contains essentially a single variant and is, therefore, more suitable for manufacture and regulatory purposes. All of the claims as amended in the set provided herewith are inventive over Clark, *et al.* In particular, the invention provides, for the first time, a human rotavirus population comprising essentially one rotavirus variant. Such a single rotavirus variant is more suitable for the formulation of consistent vaccine lots, as mentioned on page 4, lines 21-22 of the instant specification. The skilled person would have no incentive to proceed from the teaching of Clark, *et al.* to produce a single variant or substantially single variant of human rotavirus, given that Clark, *et al.* neither teaches nor

suggests the complexity of the P26 or P36 isolates from which the Applicants derived the new rotavirus population. No one in the art analyzed these isolates to establish their genetic characterization, nor were such isolates deposited in a culture collection. Accordingly, without knowledge of the present invention, the skilled person would not have proceeded to analyze the P33 and P26 isolates, and would not have arrived at the present invention. Genetic characterization by the present Applicants led to the surprising finding of a mixture of rotavirus variants, and to the isolation of a substantially single variant providing the advantages listed above.

Rule 13.2 PCT says that unity of invention is acknowledged if there is a technical relationship among those inventions involving one or more of the same or corresponding special technical feature. The Applicants assert that there is a technical novel and inventive relationship among the first three groups, and they propose by this argument that the Examiner regroup the currently claims, keeping groups I, II and III together in the current application.

SPECIES ELECTION

Although the Examiner set forth species election requirements, such requirements only pertain to Groups I and II. As the Applicants provisionally elect the claims of Group III, they need not make a species selection. Should the Applicants prevail in their traversal of the groups, and should Groups I, II, and III be joined, the Applicants will make a species election at such time.

Should the restriction become final, the Applicants reserve the right to prosecute, in one or more patent applications, the claims to non-elected inventions, the claims as originally filed, and any other claims supported by the specification. If it would advance the

prosecution of the instant application, the Examiner is invited to confer with the Applicants' undersigned patent attorney by telephone.

Respectfully submitted,

Elizabeth J. Hecht

Elizabeth J. Hecht
Attorney for Applicants
Registration No. 41,824

GlaxoSmithKline Corporation
Corporate Intellectual Property - UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939
Phone (610) 270-5009
Facsimile (610) 270-5090